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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/764,546      | 01/17/2001  | Lynn E. Spitler      | 204372000901        | 8827             |

25225 7590 06/12/2003  
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EXAMINER

UNGAR, SUSAN NMN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1642

DATE MAILED: 06/12/2003

14

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
**09/764,546**

Applicant(s)  
**Spitler et al**

Examiner  
**Ungar**

Art Unit  
**1642**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on Apr 1, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 56 and 61 is/are pending in the application.
- 4a) Of the above, claim(s) 56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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1. The Amendment filed April 1, 2003 (Paper No. 13) in response to the Letter of February 26, 2003 (Paper No. 12) is acknowledged and has been entered. Claim 61 has been added. Claim 61 is currently under prosecution.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. It is noted that Applicants believe that the subject matter of claims 56 and new claim 61 is the same. Although Applicants believe that the subject matter of withdrawn claim 56 and new claim 61 is the same, the subject matter is not found to be the same for the reasons of record, that is, that the two claims are drawn to distinct methods which differ at least in objectives, method steps, response variables and criteria for success. Further, Applicant's arguments in Paper No. 11 drawn to the rejection of claims 56 and 59 make clear that the two methods are not the same.
4. The following objection is maintained:

The specification is objected to because although Applicant amended the priority data, the status of the provisional application is not recited. Appropriate correction is required.

Objection to the Brief Description of the Drawings is held in abeyance at Applicant's request.

***New Grounds of Rejection***

***Claim Rejections - 35 USC § 102***

5. Claim 61 is rejected under 35 U.S.C. § 102(b) as being anticipated by Kleinerman et al, of record, or Kleinerman et al, of record.

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The claim is drawn to a method to ameliorate a side effect, mucositis, of antineoplasia treatment in a subject, which subject has been treated with an anti-neoplasia agent which comprises administering to said subject a pharmaceutical composition comprising MTP-PE encapsulated in multilamellar liposomes.

Kleinerman et al, 1989 teach a method of treating cancer patients comprising administering pharmaceutical compositions of MTP-PE encapsulated in multilamellar liposomes (abstract and p. 4665, col 2, see Materials and Methods) wherein the patients had been treated with antitumor therapy (p. 4665, col 2).

Kleinerman et al, 1992 teach a method of treating cancer patients comprising administering pharmaceutical compositions of MTP-PE encapsulated in multilamellar liposomes (abstract and p. 212, paragraph bridging cols 1 and 2, see Materials and Methods) wherein the patients had been treated with antitumor therapy (abstract).

The method of the prior art comprises the same method steps as claimed in the instant invention, that is, administering pharmaceutical compositions of MTP-PE encapsulated in multilamellar liposomes to the same population, that is subjects that had been treated with an anti-neoplasia agent, thus the claimed method is anticipated because the method will inherently lead to the amelioration of mucositis. See Ex parte Novitski 26 USPQ 1389 (BPAI 1993).

6. It is noted that the arguments in Paper No. 11 drawn to the rejection of claims 56 and 59 in Paper No. 9 are not relevant to the claimed invention.

7. No claims allowed.

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8. All other objections and rejections recited in Paper No. 9 are hereby withdrawn.

9. Applicant's amendment necessitated the new grounds of rejection.

Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 C.F.R.

§ 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

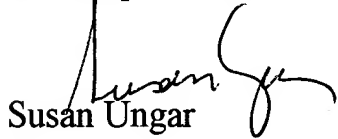
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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1640.



Susan Ungar  
Primary Patent Examiner  
June 10, 2003